APR 18 2006

Section 5
Long-Term Hemodialysis Catheters with BioBloc™ Coating
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a)

5.1 General Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ext. 5541
Fax Number:	(801) 595-5425
Contact Person:	Michaela Rivkowich
Date of Preparation:	April 12, 2006
Registration Number:	1720496
Additional Registration Numbers:	
C.R. Bard:	2212754

5.2 Subject Device Information

Device Name:	Long-Term Hemodialysis Catheters with **BioBloc™** coating
Trade Name:	**HemoSplit®, HemoStar™, BioBloc™**
Common/Usual Name:	Long-Term Hemodialysis Catheter
Classification Name:	78 MSD – Catheter, Hemodialysis, Implanted 21 CFR 876.5540(b)(1) – Class III Implanted Blood Access Device
Classification Panel:	Gastroenterology and Renal

5.3 Predicate Device Information

Device Name:	**HemoSplit®** Long-Term Hemodialysis Catheter **HemoStar™** Long-Term Hemodialysis Catheter
Trade Name:	**HemoSplit®, HemoStar™**
Common/Usual Name:	Long-Term Hemodialysis Catheter
Classification Name:	78 MSD – Catheter, Hemodialysis, Implanted 21 CFR 876.5540(b)(1) – Class III Implanted Blood Access Device
Classification Panel:	Gastroenterology and Renal

Predicate Device Name (Catheter Design)	510(k)	Clearance Date
HemoSplit® Long-Term Hemodialysis Catheter	K030020	6/16/2003
HemoStar™ Long-Term Hemodialysis Catheter	K051748	8/12/2005

The predicate device for the **BioBloc™** coating is:

Device Name:	**Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Catheter for High Volume Infusions**

Trade Name:	**Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Catheter for High Volume Infusions**
Common/Usual Name:	Two-lumen, short-term central venous hemodialysis catheter
Classification Name:	78 MPB – Nonimplanted Blood Access Device 21 CFR 876.5540 – Class II Blood Access Device
Classification Panel:	Gastroenterology and Renal

Predicate Device Name (Coating)	510(k)	Clearance Date
14 Fr Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Catheter for High Volume Infusions	K993933	9/14/2000

5.4 Intended Use

The HemoSplit® and HemoStar™ catheters are recommended for use in attaining short-term or long-term vascular access for hemodialysis, apheresis, and hemoperfusion treatments. The performance of the **BioBloc™** coating on the **HemoSplit®** and **HemoStar™** catheters in reducing bacterial adhesion for 21 days was supported by *in vitro* testing.

5.5 Indications for Use

The HemoSplit® and HemoStar™ long-term hemodialysis catheters with BioBloc™ coating are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein. Catheters greater than 40 cm are intended for femoral vein insertion.

The performance of the **BioBloc™** coating on the **HemoSplit®** and **HemoStar™** catheters in reducing bacterial adhesion for 21 days was supported by *in vitro* testing.

5.7 Device Description

The HemoSplit® and HemoStar™ catheters with BioBloc™ coating are dual lumen long-term hemodialysis catheters. Both catheters have a dual lumen, double-D cross-sectional design. The HemoSplit® catheters are designed with a split distal tip whereas the HemoStar™ catheters incorporate a staggered distal lumen tip. The catheter shaft is the same for both designs. BioBloc™ coating is present on the tunnel portion of the catheter shaft tubing. BioBloc™ coating reduces bacterial adhesion to the catheter by 99.9% in the catheter tunnel for a period of 21 days as tested in an *in-vitro* model against *Staphylococcus epidermidis, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, Enterococcus faecalis, and Escherichia coli.* Catheters with BioBloc™ coating are not intended to be used as a treatment for existing infections.

5.8 Technological Comparison to Predicate Devices

The technological characteristics of the HemoSplit® and HemoStar™ catheters with BioBloc™ coating are substantially equivalent to those of the predicate HemoSplit®, HemoStar™ and Blue FlexTip® ARROWg+ard Blue® Catheters in terms of intended use, application, user population, basic design, performance and labeling.

5.9 510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device?
Yes.

Does the new device have the same indication statement and intended use as the predicate?
The HemoSplit® and HemoStar™ catheters have the same intended use and indications for use with the addition of intended use and indications for use for BioBloc™ coating.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)?
No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, materials, etc.?
Not in all regards. The principles of operation and basic design are the same as the predicate devices. The main change in design comprises of the addition of BioBloc™ coating to the shaft of the HemoSplit® and HemoStar™ catheters. There is precedence in the market for a coated dialysis catheter (Blue FlexTip® ARROWg+ard Blue® Antimicrobial Catheter, K993933).

Could the new characteristics affect safety or effectiveness?
Yes. The design changes may affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?
No. Safety and effectiveness questions are the same as for the predicate devices.

Do accepted scientific methods exist for assessing effects of the new characteristics?
Yes. Testing was based on FDA guidance document and recognized standards to evaluate the devices' performance:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*
- *ISO 10555-1:1997, Sterile, single-use intravascular catheters, Part 1. General requirements*
- *ISO 10555-1:1997, Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 1*
- *ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- *AAMI/ANSI/ISO 10993-1:1997, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*

Are performance data available to assess effects of new characteristics?
Yes. Bench testing was based on the above referenced guidance document and standards. The testing demonstrated that BioBloc™ coating reduces bacterial adhesion to the catheter by 99.9% in the catheter tunnel for a period of 21 days as tested in an *in-vitro* model against *Staphylococcus epidermidis, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, Enterococcus faecalis, and Escherichia coli.* Catheters with BioBloc™ coating are not intended to be used as a treatment for existing infections

Performance data demonstrate equivalence?
The HemoSplit® and HemoStar™ long-term hemodialysis catheters with BioBloc™ coating met performance criteria of the safety and effectiveness tests performed and, based on FDA's decision

tree, are substantially equivalent to the predicate HemoSplit® Long-Term Hemodialysis Catheter, K030020, concurrence date 6/16/2003, HemoStar™ Long-Term Hemodialysis Catheter, K051748, concurrence date 8/12/2005, and 14 Fr Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Catheter for High Volume Infusions, K993933, concurrence date 9/14/2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2006

Ms. Michaela Rivkowich
Sr. Regulatory Affairs Specialist
Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K053589
Trade/Device Name: Long-Term Hemodialysis Catheters with **BioBloc™** Coating
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: March 28, 2006
Received: March 29, 2006

Dear Ms. Rivkowich:

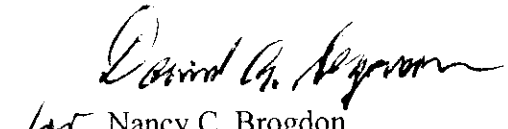
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): K053589

Device Name: Long-Term Hemodialysis Catheters with **BioBloc™** Coating

Indications for Use:

HemoSplit® and **HemoStar™** long-term hemodialysis catheters with **BioBloc™** coating are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein.

Catheters greater than 40 cm are intended for femoral vein insertion.

The performance of the **BioBloc™** coating on the **HemoSplit®** and **HemoStar™** catheters in reducing bacterial adhesion for 21 days was supported by *in vitro* testing.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053589